



Hackensack Meridian Integrative Health & Medicine

“The human body has been designed to resist an infinite number of changes and attacks brought about by its environment. The secret of good health lies in successful adjustment to changing stresses on the body.”

– Harry J. Johnson

Title of study: Personal Resilience Empowerment Program (PREP) in the perioperative setting of surgically treated cancer patients

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1. Introduction to the Personal Resilience Empowerment Program (PREP) at Hackensack Meridian Integrative Health & Medicine

The Personal Resilience Empowerment Program (PREP) at Hackensack Meridian Integrative Health & Medicine is designed to assist patients in preparing for a planned hospital admission for a surgery or procedure. The program offers classes and personal sessions where the patient, with the support of an Integrative Health Coach (Registered Nurse), is introduced to new life skills that will help him or her during their hospital experience and beyond in everyday life.

Using evidence-based tools derived from our Five Pillars of Health & Well-Being (Sleep, Activity, Purpose, Nutrition, and Resilience), the patient learns how to:

- Acquire mind-body skills to assist in stress management
- Learn to thrive by building resilience
- Feel empowered to manage their own health
- Gain self-care skills to decrease anxiety, pain, and nausea naturally
- Control the stress response and trigger the relaxation response to promote well-being
- Discover what foods fuel the body in preparation for healing, during recovery, and overall health

The goal is for the patient to leave the coaching sessions feeling empowered to use new tools to elicit the relaxation response or build on resiliency practices they may already use.

The program is led by integrative health coaches/registered nurses who will help to facilitate and motivate the patient to make positive choices for overall health and wellness. They educate and support group members to achieve their goals through lifestyle and behavior adjustments. Health coaching brings together several disciplines including sleep, activity, purpose, nutrition, resilience. There is no cost for the class.

2. Introduction to the PREP project

The PREP at Hackensack Meridian Integrative Health & Medicine was designed in Legacy Meridian to assist all selected patients with upcoming hospitalization. For the “Personal Resilience Empowerment Program (PREP) in the perioperative setting of surgically treated cancer patients”, hereafter “the Project or PREP”, the Hackensack Meridian Integrative Health & Medicine is designing a new pilot program to focus on the needs of oncology patients.

All patients diagnosed with cancer that will undergo a scheduled surgical (Hepato-Biliary, and Thoracic) procedure in Hackensack Meridian Health and specifically in the Jersey Shore University Medical Center, will be eligible to participate (for more details please see eligibility criteria, section 4).

Overall, this pilot project will include 5 coaching sessions and an introductory session/visit that will take place on the physician’s office. The initial physician visit will focus on patient eligibility, introduction to

the Project, informed consent and a pre-intervention survey and will be conducted by the principal investigator or one of the sub-investigators listed above. The following 5 sessions will be conducted by one of the integrative health coaches/registered nurses (for details please see section 5). A post-intervention survey will be completed during the final session and repeated at one month, and at 3 months from the final session.

The goal of this project is to investigate whether using the PREP as an intervention in patients diagnosed with cancer would result in improving various metrics including improvements to resilience, sleep, activity, purpose, nutrition, empowerment to manage one's own health and well-being, decrease in pain medication use and more rapid return to previous functional status according to Eastern Cooperative Oncology Group (ECOG).

3. Study Purpose and Objectives

3.1. Purpose of the study

This is a pilot study designed to assess the effectiveness of the Personal Resilience Empowerment Program (PREP) in supporting surgical oncology patients before, during and after their hospitalization.

3.2. Primary objectives

The primary objective of this project is to determine if an increase in knowledge and awareness through coaching sessions improves quality of life by empowering the person to manage one's own health in the application of skills related to our 5 pillars of Health and Wellbeing. (sleep, activity, purpose, nutrition, resilience) in oncology patients.

3.3. Primary and Secondary Endpoints

Measurements of health related quality of life, sleep, activity, purpose, nutrition, resilience and empowerment to manage one's own health and well-being at 1 month and 3 months from final session. Also pain, use of pain medication and return to work-more rapid return to previous pre-operative functional status according to ECOG. In addition, record the number of times (if any) that nurse coaches are called for support outside of the protocol.

4. Study Participants

4.1. Study population

All patients who will undergo a scheduled surgical, thoracic (lung), hepato-biliary (cholangiocarcinoma, pancreatic, liver) procedure in Hackensack Meridian Health at Jersey Shore University Medical Center that meet the inclusion criteria will be invited to participate in this project.

Initial contact with potential participants will take place at each surgeon's office and every surgeon listed as investigator/sub-investigator in this protocol will present the study to his/her patients and will consent them.

4.2. Number of participants

This project is a pilot to assess the effectiveness of the PREP to support oncology patients before, during and after their hospitalization

Five to six new patients are seen on a weekly basis in the physician practices. We plan to run this project for 3 months, therefore taking into consideration patients' willingness to participate and complete all sessions and the number of potential losses during follow-up, we estimate that we will include 30-40 patients but no more than 50 patients.

4.3. Selection Criteria

Inclusion Criteria

1. 18 years of age and older
2. Patients diagnosed with cancer of the thoracic (lung), hepatobiliary system (cholangiocarcinoma, pancreatic, liver) that will undergo a scheduled surgical procedure at Jersey Shore University Medical Center.
3. Able to understand and sign the informed consent form
4. Willingness to participate in the study and comply with protocol requirements

Exclusion Criteria

1. < 18 years of age
2. Unable to provide consent
3. Unable to participate at the discretion of the PI based on the ECOG survey (if ECOG >1). See section 5 and appendix 1 for details.
4. Non- English speaking patients¹.
5. Opioid use for non-malignant pain for greater than 7 days 6 Terminal or Stage 4 cancer.

¹ Participants will be limited to English-Speaking patients only for this pilot phase as current resources do not allow the support of foreign speaking patients.

5. Study Design

5.1. Study Overview

This is a pilot study designed to assess the effectiveness of the PREP in supporting surgical oncology patients before, during, and after their hospitalization.

The project includes 5 sessions with a RN Health Coach. The overview of the study is summarized in table 1 below. The initial pre-operative physician visit will focus on patient eligibility, introduction to the Project, informed consent and a pre-intervention survey and will be conducted by oncology surgeon or physician assistant. The remaining sessions will be conducted by one of the integrative health coaches/registered nurses. A post-intervention survey will be completed during the final session.

In addition to the basic demographics being collected, the following clinical information will also be collected for every patient across multiple time points: AJCC cancer stage, occurrence of chronic pain (if applicable), pain level (using a scale 0-10), pain medication usage (yes/ no), pain medication type used (prescription or over the counter), and pain medication dosage and frequency for each pain medicine listed (where applicable).

The goal of this project is to investigate whether using the PREP as an intervention in patients diagnosed with cancer would result in improving various metrics including improvements to health related quality of life, sleep, activity, purpose, nutrition, resilience, and empowerment to manage one’s own health and well-being, decrease in pain medication use and more rapid return to previous functional status.

For details about each session and what will be covered please see below (section 5.4.).

For details on the study timeline, please see below.

Table 1: Study schedule

Study-related activity	# of session	Type of session	Procedure	Timeline
1	-	Eligibility visit	Initial pre-operative visit at surgeon’s office to include: determination of patient eligibility, introduction into the study, informed consent, pre-intervention survey	Prior to surgery
			Pre-intervention survey	
2	1	In-person coaching	Group PREP coaching class Introduction to 5 pillars of health & well-being	Prior to surgery
3	2	Over the phone coaching	Review of the Basic Pillars and validating learned skills from group session.	Within one week of visit #1.
<i>Scheduled surgical procedure</i>				
4	3	In-person coaching	Review of all the skills, focus on skills for support during the hospital stay.	Within one week after surgery
5	4	Over the phone coaching	Follow-up after the surgery reinforcing the new life-skills	Within one week from discharge
6	5	In-person coaching	Review of the skills, coaching for integration into everyday life.	Within two weeks from discharge at post-operative visit
			Post-intervention survey	
7	-	Survey	Follow-up survey (hard copy)	One month after the surgery
8	-	Survey	Follow-up survey (hard copy)	3 months after the surgery

5.2. Study Duration

The expected study duration is three months. After informed consent, participants will fill out the pre-intervention survey and then they will attend five coaching sessions either in person or over the phone. Participants will fill the post-intervention survey during their last session. Two follow-up surveys will be sent to enrolled participants one month and three months after the last session.

5.3. Study Sites

This project will take place in:

- Jersey Shore University Medical Center, 1945 Route 33, Neptune, NJ 07753
- Riverview Medical Center, 1 Riverview Plaza, Red Bank, NJ 07701
- Medical Arts Building , 1944 Route 33, , Neptune, NJ 07753
- Integrative Health & Medicine, 16 Spring Street, Red Bank, NJ 07701

5.4. Study visits / sessions

As described earlier, this project will include one initial visit focusing on patient eligibility, study presentation and informed consent followed by 5 coaching sessions that will take place either in-person or over the phone.

The initial visit will be conducted by one of the oncology surgeons listed as investigators in this protocol, while the coaching sessions will be conducted by one of the Nurse Health Coaches from Integrative Health & Medicine.

Attendance and the duration of each session will be recorded in a Word document.

5.4.1. Research Eligibility

The research eligibility will take place in the office of each one of the surgeons listed in this protocol. Following consent based on research eligibility, all participants will complete the pre-intervention survey.

More specifically, the surgeon will present the study using the script presented below.

The Personal Resilience Empowerment Program (PREP) will assist you in preparing for your upcoming hospital admission. You will learn and practice skills that you can use beyond your surgery or procedure in your everyday life. We look at this health event as an opportunity to examine your lifestyle choices and build your awareness of the mind/body connection so you can become empowered to manage your own health. You will be contacted by telephone by a Registered Nurse (RN) health coach to schedule an in-person group coaching and telephone coaching session within one week of this consent. During the group session, you will be introduced to our five pillars of health and well-being: sleep, activity, purpose, nutrition and resilience. Following the group session and prior to your surgery, you will have a phone call with the nurse health coach. In this phone call, the RN health coach will reinforce our five pillars of health and well-being and discuss how you and the coach will partner throughout this process. In total, you will meet with the nurse health coach five times-first during a group coaching class, and then session 2 will be a phone coaching session within one week prior to your surgical admission, session 3 will be in person hospital coaching session, session 4 will be a phone coaching session within one week of discharge and the fifth session will be in person at your post-operative hospital visit . Our goal is to assist you in developing resilience skills that can help you bounce back and

assist you in managing stress, reducing potential pain and empowering you to improve your quality of life.

Patients that are interested in taking part in the study will be then consented by the surgeon or another member of the study team and will be notified of the study procedures (upcoming 5 sessions). They will be asked to provide their contact details including their email and a contact number.

To facilitate the information and engagement process, the surgeon will also provide enrolled patients with the “The Personal Resilience Empowerment Program (PREP) flyer”.

At the end of the information process, the surgeon will notify patient that the Registered Nurse - Health Coach will contact them to schedule the initial group session within one week and telephone session to be completed prior to surgery.

Finally, patients will be asked to fill the pre-intervention survey at the end of the session. Participants will be provided with hardcopies of the surveys and data collected will then be transferred to a database created specifically for this project in Excel.

After the end of the research eligibility visit, the nurse coach will receive a spreadsheet of patients enrolled in the study by the physician office following consent

5.4.2. First session

The first session is a group coaching class prior to surgery. After an overall presentation of the program, the class will focus on introducing the 5 pillars of health and well-being: sleep, activity, purpose, nutrition and resilience. Several handouts will be provided for patients to take home and use between sessions. All handouts and the PowerPoint presentation for this session will be submitted to the IRB for approval.

This is a 90 minute class held at Jersey Shore University Medical Center. During the group PREP class, participants will learn how to acquire mind-body skills to assist in stress management, learn to thrive by building resilience, feel empowered to manage their health, gain self-care skills to decrease anxiety, pain and nausea naturally, control the stress response and trigger the relaxation response to promote well-being and discover what foods fuel the body in preparation for healing, during recovery and overall health.

5.4.3. Second session

The second session will take place over the phone.

During the second session, the nurse coach after a quick overview of the group session will focus on the coaching needs of the patient at that time. The coach will address the readiness to change and will reinforce the skills taught in the group class.

To facilitate the discussion and ensure consistency across patients, the nurse coach will use a script (see appendix 2).

The call is expected to last approximately 30 minutes (but not more than 60 minutes). The total time of the session will be documented and recorded in the patient’s research file. The nurse health coach will complete a health coach consult note in research file.

5.4.4. Third session

The third session will be an in-person hospital visit with the nurse health coach and will occur 3-5 days following the surgical procedure. The session will last 15-30 minutes (but not more than 60 minutes).

During the session, the nurse coach will re-introduce the skills and he/she will practice those skills with the patient. To facilitate the discussion and ensure consistency across patients, the nurse coach will use a script (see appendix 3). The nurse health coach will encourage and empower the patient to use these skills throughout the remainder of the stay and beyond. Coach will offer additional support as appropriate.

In the end of the session, the nurse will remind the patient that they will receive a telephone call after discharge to schedule the fourth session over the phone. The patient will also be offered the opportunity to call the nurse-coach if they feel like they need additional support at any time throughout this program.

5.4.5. Fourth session

The health coach will be notified of the patients discharge date from the surgeon's office and the health coach will contact the patient to schedule a telephone coaching session within one week of the discharge. To facilitate the discussion and ensure consistency across patients, the nurse coach will use a script (see appendix 4).

The fourth session will be over the phone and will last approximately 15-30 minutes (but not more than 60 minutes). During the session, the nurse-coach will focus on the skills and will encourage and empower the patient that these can be used for relaxation, stress management and to build and sustain resilience beyond the hospital experience. Coach will offer additional support as appropriate.

5.4.5. Fifth session

Session 5 will be in-person and will take place the same day as the follow-up doctor's appointment and will last 15-30 minutes (but not more than 60 minutes).

The nurse-coach will conclude the program, remind patient of the techniques learned and will also encourage and empower the patient that these are life skills that can be used for relaxation, stress management and to build and sustain resilience. Coach will offer additional support as appropriate after the end of the study. To facilitate the discussion and ensure consistency across patients, the nurse coach will use a script (see appendix 5).

In the end of the final session, the patient will be asked to complete a hard copy of the exit survey (post-intervention).

5.4.6. Follow-up

Patients will be sent a hard copy of the follow-up survey to the address they have provided at one and three months after discharge.

6. Methods

6.1. Survey

All surveys used were created for this project. The majority of the questions are influenced by questions found in validated tools such as the CDC Quality of Life tool and have been adjusted to reflect the needs of oncology patients.

6.1.1. Survey Construction

All instruments are novel and were developed solely for this project. Questions were developed through consultation with the investigator team, subject matter experts, and relevant literature.

6.1.2. Survey Administration

The surveys will be administered during the initial visit and at the last coaching session. Two more follow-up surveys will be sent to participants at one and three months after discharge. Participants will be provided with hardcopies of the surveys and data collected will then be transferred to a database created specifically for this project in Excel.

6.2. Statistical Design

The proposed study will be a descriptive case-series of thoracic and hepatobiliary oncology patients who are scheduled to undergo surgical intervention at Jersey Shore University Medical Center, a hospital in the Hackensack Meridian Health Network, that will be enrolled in the Personal Resilience Empowerment Program (PREP).

6.2.1 Sample Size

The sample size proposed for this study is as many patients as can be recruited by the end of March 2018 or a maximum of 50 patients, whichever occurs first. Given that this is a pilot study for the PREP initiative at Hackensack Meridian Health there is no existing data with which to calculate a precise sample size that would be needed to provide statistical power. Therefore, we relied heavily upon the number of patients who could be approached during the study consent timeframe, with consideration for both potential drop-out and loss to follow-up, as well as the challenge of consenting patients in the first place, to determine the potential sample size.

6.2.2 Planned Analyses

6.2.2.1 Interim Analysis

Due to the nature of the study design, there is no interim analysis planned.

6.2.2.2 Analysis Methods

Continuous measures and outcomes will first be summarized using minimum, maximum, mean, standard deviation, median, and interquartile range, while categorical and ordinal measures will first be summarized using frequencies and percentages. For any patient measure that can be described as a time to an event, the median time will be estimated using the Kaplan-Meier procedure with the standard error being estimated by the Greenwood formula.

In order to detect significant changes in the longitudinal repeated measurements from the pre- and post-intervention patient survey, McNemar or Stewart-Maxwell tests will be used for categorical measures while Wilcoxon Signed Rank Tests will be used for ordinal measures. Any continuous measures

will be compared using either a paired T-Test or a Wilcoxon Signed Rank Test depending on the outcome of the Shapiro-Wilk test of normality.

In addition, a cancer stage stratified analysis is currently planned. The normality of each continuous measure will first be tested using the Shapiro-Wilk test. Given that the variable can be considered normally distributed, either a T-test or an ANOVA test will be used to compare the continuous measure between the stage groups, dependent upon how many stages are represented in the patient sample. However, if the measure cannot be considered normally distributed, then the Wilcoxon rank sum test or Kruskal-Wallis test will be used instead. For all categorical variables, we will first consider using the Pearson's Chi-Square test. However, if any expected frequency within the contingency table is less than 5 then the Fisher's exact test will be used. For any ordinal variables with more than 2 potential outcomes the Wilcoxon rank sum test or Kruskal-Wallis test will be used.

A two-sided p-value will be reported for each test result using a potential Type 1 error of $\alpha = 0.05$. Any p-value shown to be less than α will be considered statistically significant. As necessary, graphical representations of results will be provided.

6.2.3 Data Relevance

The data elements being collected are both clinical and patient self-reported measures. The clinical aspects that are proposed will allow the study team to better ascertain the patients' health condition pre-operatively and post-operatively during the most critical timeframes for preparation and recovery, respectively. These pieces of information are vital in being able to describe the study population and understand the clinical experience of the participants. Whereas the self-reported measures that are proposed for collection, via surveys, will provide the study team with more of an understanding of the patients' awareness of the effects of the 5 Pillars (Activity, Nutrition, Sleep, Purpose, and Resilience), as well as their feelings towards making changes in their life based on the PREP coaching process. Additionally, the follow-up surveys will allow the team to gain information from the patient on how they are recovering as well as how they can improve PREP for future patient participants.

6.2.4 Data Coding

6.2.4.1 Data De-identification

All study data will be de-identified prior to analysis by assigning a unique and generic study identifier to each patient upon enrollment into the study. This assigned number will not contain or be linked to any personal health identifiers (PHI). A coded list containing the matching information between the generic study identifier and the true identity of the patient will be kept on a Hackensack Meridian Health password protected network computer and will not be shared with the study biostatistician or anyone else performing data analyses.

6.2.4.1 Data Element Coding

All clinical study data will be recorded as it is written in the patient chart, lab test report, or pathology report. However, we may later create or recode measures that indicate the presence or the lack of presence of something specific pre- or post-operatively as 0 (not present) and 1 (present). This could include the presence of certain comorbidities that may affect the coaching process or surgical outcomes.

For coaching follow-up notes and survey data, the responses that are requested from the patient are largely from a 0 – 5 Likert Scale (with some written explanation) and will be coded as such. For any

questions that elicit an affirmative response (i.e.: yes) or a negative response (i.e.: no) the measures will also be coded as a 0 or 1.

6.2.5 Data Analysis Tools

Data collection and storage will be performed using Microsoft Word and Microsoft Excel. All documents will be saved in password protected computers only accessible to the study team.

Statistical analysis will be performed using:

1. SAS software Version 9.4 of the SAS System for Windows (SAS Institute Inc. [2012], Cary NC, USA. URL www.SAS.com)
2. R language for statistical computing (R Core Team [2017]. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria. URL <http://www.R-project.org/>)

7. Ethical Considerations

The study will be conducted according to the International Conference on Harmonization (ICH), Good Clinical Practice (GCP), the Declaration of Helsinki, Institutional Review Boards (IRB) and in accordance with the U.S. Code of Federal Regulations on Protection of Human Rights (21 CFR 50).

7.1. Institutional Review Board (IRB) Review

The final study protocol, surveys and collection tool will be approved by the Institutional Review Board (IRB) at Jersey Shore University Medical Center. Approval will be received in writing before initiation of the study.

Any changes to the study design will be formally documented in protocol amendments and approved by the IRB prior to implementation.

7.2. Data Management

All data will be stored on a Hackensack password protected computer only accessible by the investigator team.

Jersey Shore UMC password protected computers are only accessible by the P.I. and/or research staff. Data collected will be maintained securely with limited access. Records will be retained in accordance with regulatory, organizational and sponsor requirements, but no less than six (6) years following the completion of the research. Disposal of records will be done in such a manner that no identifying information can be linked to research data.

7.3. Informed consent

A signed informed consent shall be obtained from each participant prior to entering the study. The informed consent forms provides information and explanations of the aims, methods, anticipated benefits and potential hazards of the study.

Before any protocol-specific screening procedures are administered, information will be given to all potential participants during the study introduction taking place in the first session.

The acquisition of informed consent will be documented in the participant's record and the informed consent form will be signed and personally dated by the participant and by the person who conducted the informed consent discussion. The original signed form will be retained in the Investigator Site File and a copy of the original will be provided to the participant prior to participation in the study.

The participants will be informed that they may withdraw from the study at any time without prejudice and compilation of that person's data will cease as of the date of his/her written request for withdrawal.

7.4. Confidentiality

The patient charts, collected data and all analysis of the data will adhere to HIPAA & institutional patient confidentiality requirements.

More specifically, a coding system will be used for which a unique identifier (study number) will be assigned to each name and contact details. Each participant whose data is collected will be assigned a unique study number. Only the study number will be included in the data collection tool, data analysis tools, and potential publications. The list with the direct identifiers (for the purposes of linking data with the surveys and keeping track of the devices) will also be stored in a secured server in the Jersey Shore University Medical Center, Center for Integrative Medicine, in a separate file.

Analytical datasets will be stored on secure servers that also limit access to the investigator team. Should results of the study be published or reported, individual names or other identifying information will not be used.

Appendix 1 – ECOG Performance Status

Developed by the Eastern Cooperative Oncology Group, Robert L. Comis, MD, Group Chair.*

GRADE	ECOG PERFORMANCE STATUS
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities; up and about more than 50% of waking hours
3	Capable of only limited selfcare; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any selfcare; totally confined to bed or chair
5	Dead

*Oken M, Creech R, Tormey D, et al. Toxicity and response criteria of the Eastern Cooperative Oncology Group. *Am J Clin Oncol.* 1982;5:649-655.

Appendix 2 – Handout and Script for Session No 2

Session 2- Phone call within one week prior to surgical admission with nurse health coach (at least 30, not more than 60 minutes)

“Hi my name is _____ and I am a Registered Nurse Health Coach. We will partner throughout this process to help you bounce back and assist you in managing stress, reducing potential pain and empowering you to improve your quality of life. Today, in our second session, we will review the skills from the group class and I will provide you with support around the skills. In the class, you learned the five pillars of health and well-being that can support you to manage your upcoming surgery. These are life skills which you can apply during your upcoming hospital admission and beyond your hospital experience. To begin, let’s look at your pain, anxiety and well-being. How would you rate your pain right now from 0-10 with 0 being no pain and 10 being the worst pain? How about your anxiety level from 0-10? If 0 is no anxiety and 10 is severe anxiety, how would you rate how you feel right now? How about your sense of well-being? From 0-10 with 0 meaning not well and 10 being well, what number would you rate yourself right now?

We are now going to discuss the five pillars of health and well-being by looking at the Mind Body Spirit reference guide which you received at the PREP group coaching class. Let’s start by discussing your sleep which is essential for the body to heal, repair, and prepare for the next day. How are you sleeping? [Coach will offer support as appropriate]

Our next pillar is activity. Activity is more than exercise; it includes your movement throughout the day. Movement is important for your body but it is also important for your mind. When you move, chemicals are released which improve your emotions and your brain function. What is your current activity level? Has your doctor given you any restrictions on your activity? [Coach will offer support as appropriate]

Our third pillar is purpose. Purpose is where you find meaning in your life; it’s what gets you out of bed in the morning. When we are clear on our values, strengths and our sense of purpose, it can help serve as an anchor in tough times. Sometimes when we experience challenges such as a health event, it is a time where we re-examine our purpose. We can apply this to the purpose for your upcoming admission, or beyond to your greater life purpose. I would encourage you in the time before your surgery and in our future sessions to reflect on your purpose. [Coach will offer support as appropriate]

Our fourth pillar, nutrition, is the fuel for our mind and body. You can refer to the food that increase and decrease inflammation sheet that was provided to you. How is your nutrition intake? In general, foods like breads, pastas, dairy, processed meats, red meats, soy oil, corn oils, fast and fried food, and soft drinks and sugary beverages turn on inflammation in our body. Inflammation over time can lead to disease. The food choices you make now can help you in preparation for your wound healing and your body’s natural response to surgery. By choosing to eat things like nuts, avocados, spinach, tart cherries, pineapple, orange vegetables and fruit, and

turmeric, onion, ginger and garlic you can help your body to heal faster since these foods decrease inflammation and promote healing. [Coach will offer support as appropriate]

The fifth pillar is resilience which is the ability to cope and bounce back in difficult times. How do you currently handle/manage your stress? [Coach will offer support as appropriate] To counteract your stress response, we are going to practice skills that can create balance in your body and mind. We are going to practice the 4-7-8 breathing technique which you learned in the group PREP class that will help relax you.

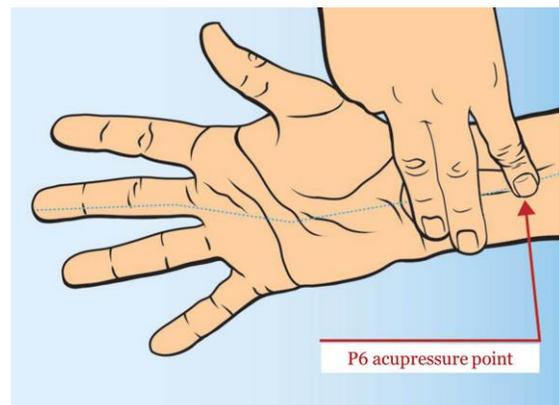
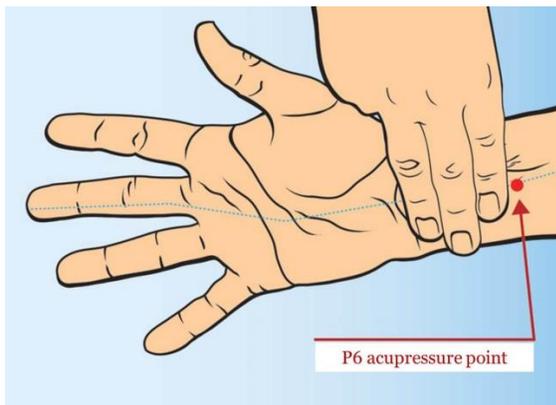
The key to doing this exercise properly is to ensure that your exhalation is twice as long as your inhalation. Let's take out the 4-7-8 breathing card now. [The nurse health coach will guide the patient through the following exercise]:

1. Sit or lie comfortably with your back straight.
2. Place the tip of your tongue against the ridge of tissue just behind your upper front teeth and keep it there throughout the entire exercise.
3. Exhale completely through your mouth.
4. Close your mouth lightly and inhale through your nose quietly to a count of 4.
5. Hold your breath for a count of 7.
6. Exhale audibly through your mouth for a count of 8.
7. Repeat steps 4-6 three more times for a total of four breath cycles.
8. Breathe normally and observe how your body feels.

Try using this twice per day and any other time you want to relax your body and mind. You can use this if you are experiencing pain or anticipating pain. It may also help calm your mind prior to sleep. By focusing on your breath, you can allow your mind to settle down and rest.

Next we will practice using the pressure point located on your inner forearm between the two tendons.

Apply firm pressure to this area on the inside of your wrist to help with nausea and/or vomiting from: upset stomach, motion sickness, chemotherapy or after surgery due to the effects of anesthesia.



Step 1: Find the point, three finger widths from base of wrist.

Step 2: Now feel the center of the two tendons with the index finger. Apply pressure with your pointer finger. It is common to feel a dull aching sensation at the point. Stimulate this point with moderate to firm pressure with your fingertips in a circular motion and repeat the movement on each wrist for at least 30 seconds and up to 2 minutes. The treatment can be used as often as needed. Once you know the location of the point, some people find it is easier to use their thumb to apply the pressure.

Make sure to ask your health care provider exactly how to use these mind-body techniques.

Please remember our third session will be in-person in your hospital room midway during your hospital stay. At this time we will check in with your pain, anxiety and well-being and practice the skills we discussed in this call in addition to other coaching support you may need. Our fourth session will take place over the phone within one week of your discharge. I will call you once I'm notified that you have been discharged to schedule a phone coaching session within one week. At this session we will discuss the transition of the skills you learned and used in the hospital to your everyday life. I will check in again on your pain, anxiety and well-being and offer additional support as needed. The final session will be in person at your first post-operative doctor visit. I will meet you in the office for a coaching session at this time to review the skills you have learned, and check in on your pain, anxiety and well-being. You will also be requested to complete a program evaluation and follow-up survey. If you feel like you need additional support at any time throughout this program, you can call me at _____.

Appendix 3 – Script for Session No 3

Session 3 –In-person hospital visit with nurse health coach (at least 15 minutes, not more than 60 minutes)

“Hi, Mr. or Mrs. _____, I am _____, a Registered Nurse Health Coach . Let’s check in on how you’re doing and if you’ve used the techniques we discussed and practiced in the group PREP coaching class and over the phone. How would you rate your pain right now from 0-10 with 0 being no pain and 10 being the worst pain? How about your anxiety level from 0-10? If 0 is no anxiety and 10 is severe anxiety, how would you rate how you feel right now? How about your sense of well-being? From 0-10 with 0 meaning not well and 10 being well, what number would you rate yourself right now? [Nurse Health coach will report findings to primary RN]. Let’s start by reviewing the 5 pillars of health and well-being. Sleep which is essential for the body to heal, repair, and prepare for the next day. How are you sleeping? [Coach will offer support as appropriate]

Our next pillar is activity. What is your current activity level? Has your doctor given you any restrictions on your activity? [Coach will offer support as appropriate]

Our third pillar is purpose. Did you create/are you using your purpose statement? [Coach will offer support as appropriate]

Our fourth pillar, nutrition, is the fuel for our mind and body. How is your nutritional intake?[Coach will offer support as appropriate]

The fifth pillar is resilience which is the ability to cope and bounce back in difficult times. How are you currently handling/managing your stress? [Coach will offer support as appropriate]

Have you used the techniques we practiced prior to surgery? Which skill(s)? How often did you use it? Would you like to practice one of the skills now together?” [Coach will review skill(s) as patient self-directs].

To counteract your stress response, we are going to practice skills that can create balance in your body and mind. We are going to practice the 4-7-8 breathing technique which you learned in the group PREP class that will help relax you.

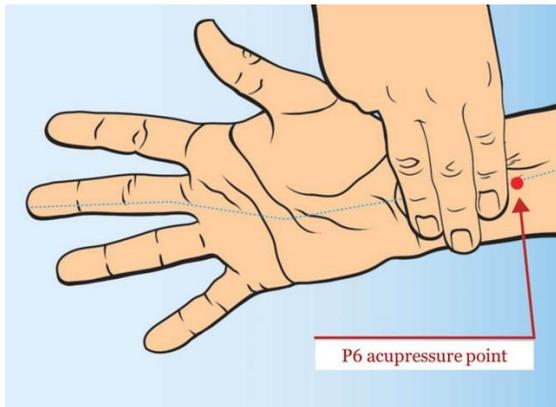
The key to doing this exercise properly is to ensure that your exhalation is twice as long as your inhalation. Let’s take out the 4-7-8 breathing card now. [The nurse health coach will guide the patient through the following exercise]:

1. Sit or lie comfortably with your back straight.
2. Place the tip of your tongue against the ridge of tissue just behind your upper front teeth and keep it there throughout the entire exercise.
3. Exhale completely through your mouth.
4. Close your mouth lightly and inhale through your nose quietly to a count of 4.
5. Hold your breath for a count of 7.

6. Exhale audibly through your mouth for a count of 8.
 7. Repeat steps 4-6 three more times for a total of four breath cycles.
 8. Breathe normally and observe how your body feels.
- Try using this twice per day and any other time you want to relax your body and mind. You can use this if you are experiencing pain or anticipating pain. It may also help calm your mind prior to sleep. By focusing on your breath, you can allow your mind to settle down and rest.

Next we will practice using the pressure point located on your inner forearm between the two tendons.

Apply firm pressure to this area on the inside of your wrist to help with nausea and/or vomiting from: upset stomach, motion sickness, chemotherapy or after surgery due to the effects of anesthesia.



Step 1: Find the point, three finger widths from base of wrist.

Step 2: Now feel the center of the two tendons with the index finger. Apply pressure with your pointer finger. It is common to feel a dull aching sensation at the point. Stimulate this point with moderate to firm pressure with your fingertips in a circular motion and repeat the movement on each wrist for at least 30 seconds and up to 2 minutes. The treatment can be used as often as needed. Once you know the location of the point, some people find it is easier to use their thumb to apply the pressure.

Make sure to ask your health care provider exactly how to use these mind-body techniques.

[The nurse health coach will encourage and empower the patient to use these skills throughout the remainder of the stay and beyond. Coach will offer additional support as appropriate].

You will receive a telephone call after discharge to schedule the fourth session with me over the phone. If you feel like you need additional support at any time throughout this program, you can call me at

_____.

Appendix 4 – Script for Session No 4

Session 4-Phone call within one week of discharge with nurse health coach (at least 15 minutes, not more than 60 minutes)

“Hi, Mr. or Mrs. _____, I am _____, a Registered Nurse Health Coach. Let’s check in on how you’re doing and if you’ve used the techniques we discussed and practiced over the phone and in person. How would you rate your pain right now from 0-10 with 0 being no pain and 10 being the worst pain? How about your anxiety level from 0-10? If 0 is no anxiety and 10 is severe anxiety, how would you rate how you feel right now? How about your sense of well-being? From 0-10 with 0 meaning not well and 10 being well, what number would you rate yourself right now? Have you used the techniques we practiced since our last visit? Which skill(s)? How often did you use it?

Let’s review again the 5 pillars of health and well-being. Sleep which is essential for the body to heal, repair, and prepare for the next day. How are you sleeping? [Coach will offer support as appropriate]

Our next pillar is activity. What is your current activity level? Has your doctor given you any restrictions on your activity? [Coach will offer support as appropriate]

Our third pillar is purpose. Did you create/are you using your purpose statement? [Coach will offer support as appropriate]

Our fourth pillar, nutrition, is the fuel for our mind and body. How is your nutrition? [Coach will offer support as appropriate]

The fifth pillar is resilience which is the ability to cope and bounce back in difficult times. How are you currently handling/managing your stress? [Coach will offer support as appropriate]

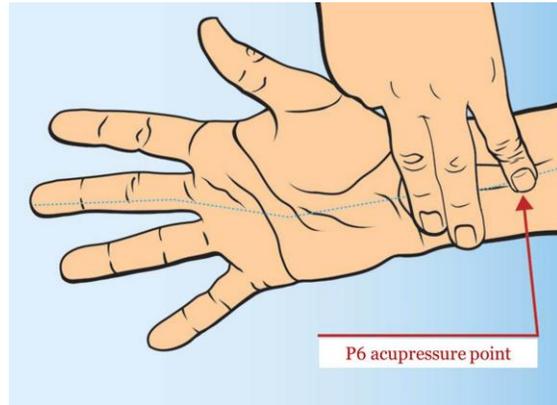
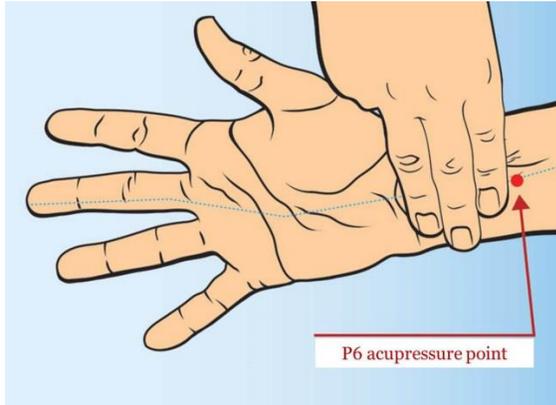
Let’s practice two of resilience techniques now again. Let’s start with the 4-7-8 breathing. As you may remember, the key to doing this exercise properly is to ensure that your exhalation is twice as long as your inhalation. [The nurse health coach will guide the patient through the following exercise]:

1. Sit or lie comfortably with your back straight.
2. Place the tip of your tongue against the ridge of tissue just behind your upper front teeth and keep it there throughout the entire exercise.
3. Exhale completely through your mouth.
4. Close your mouth lightly and inhale through your nose quietly to a count of 4.
5. Hold your breath for a count of 7.
6. Exhale audibly through your mouth for a count of 8.
7. Repeat steps 4-6 three more times for a total of four breath cycles.
8. Breathe normally and observe how your body feels.

By focusing on your breath, you can allow your mind to settle down and rest.

The next skill we will practice is a pressure point located on your inner forearm between the two tendons.

Apply firm pressure to this area on the inside of your wrist to help with nausea and/or vomiting from: upset stomach, motion sickness, chemotherapy or after surgery due to the effects of anesthesia.



Step 1: Find the point, three finger widths from base of wrist.

Step 2: Now feel the center of the two tendons with the index finger. Apply pressure with your pointer finger. It is common to feel a dull aching sensation at the point. Stimulate this point with moderate to firm pressure with your fingertips in a circular motion and repeat the movement on each wrist for at least 30 seconds and up to 2 minutes. The treatment can be used as often as needed. Once you know the location of the point, some people find it is easier to use their thumb to apply the pressure.

Make sure to ask your health care provider exactly how to use these mind-body techniques.

[The nurse health coach will encourage and empower the patient that these are skills that can be used for relaxation, stress management and to build and sustain resilience. Coach will offer additional support as appropriate]

Our final session will be in person at your follow-up appointment with your surgeon. If you feel like you need additional support at any time throughout this program, you can call me at _____."

Appendix 5 – Script for Session No 5

Session 5-In-person post-operative visit with nurse health coach at follow-up doctor's appointment (at least 15 minutes, not more than 60 minutes)

"Hi, Mr. or Mrs. _____, I am _____, a Registered Nurse Health Coach Let's check in on how you're doing and if you've used the techniques we discussed and practiced over the phone and in the hospital. How would you rate your pain right now from 0-10 with 0 being no pain and 10 being the worst pain? How about your anxiety level from 0-10? If 0 is no anxiety and 10 is severe anxiety, how would you rate how you feel right now? How about your sense of well-being? From 0-10 with 0 meaning not well and 10 being well, what number would you rate yourself right now? Have you used the techniques we practiced since our last visit? Which skill(s)? How often did you use it?

Let's review again the 5 pillars of health and well-being. Sleep which is essential for the body to heal, repair, and prepare for the next day. How are you sleeping? [Coach will offer support as appropriate]

Our next pillar is activity. What is your current activity level? Has your doctor given you any restrictions on your activity? [Coach will offer support as appropriate]

Our third pillar is purpose. Did you create/are you using your purpose statement? [Coach will offer support as appropriate]

Our fourth pillar, nutrition, is the fuel for our mind and body. How is your nutrition? [Coach will offer support as appropriate]

The fifth pillar is resilience which is the ability to cope and bounce back in difficult times. How are you currently handling/managing your stress? [Coach will offer support as appropriate]

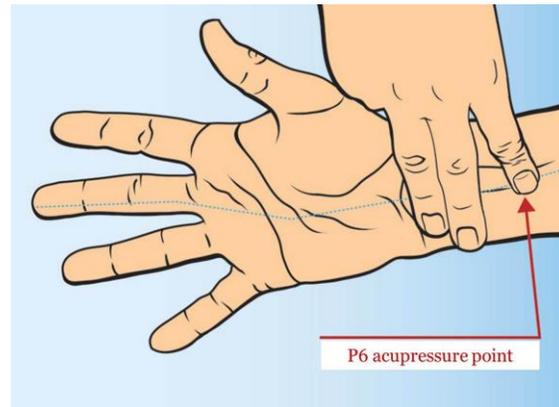
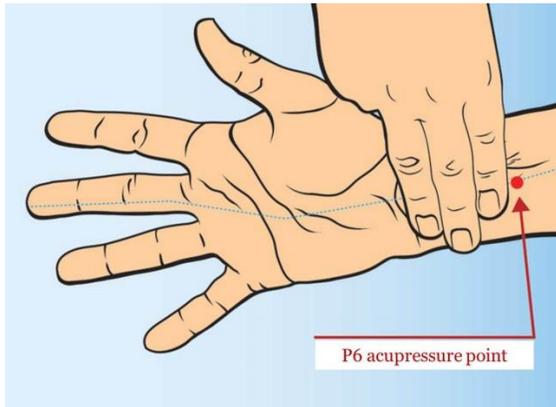
Let's practice two of those techniques now again. Let's begin with the 4-7-8 breathing. As you may remember, the key to doing this exercise properly is to ensure that your exhalation is twice as long as your inhalation. [The nurse health coach will guide the patient through the following exercise]:

1. Sit or lie comfortably with your back straight.
2. Place the tip of your tongue against the ridge of tissue just behind your upper front teeth and keep it there throughout the entire exercise.
3. Exhale completely through your mouth.
4. Close your mouth lightly and inhale through your nose quietly to a count of 4.
5. Hold your breath for a count of 7.
6. Exhale audibly through your mouth for a count of 8.
7. Repeat steps 4-6 three more times for a total of four breath cycles.
8. Breathe normally and observe how your body feels.

By focusing on your breath, you can allow your mind to settle down and rest.

The next skill we will practice is a pressure point located on your inner forearm between the two tendons.

Apply firm pressure to this area on the inside of your wrist to help with nausea and/or vomiting from: upset stomach, motion sickness, chemotherapy or after surgery due to the effects of anesthesia.



Step 1: Find the point, three finger widths from base of wrist.

Step 2: Now feel the center of the two tendons with the index finger. Apply pressure with your pointer finger. It is common to feel a dull aching sensation at the point. Stimulate this point with moderate to firm pressure with your fingertips in a circular motion and repeat the movement on each wrist for at least 30 seconds and up to 2 minutes. The treatment can be used as often as needed. Once you know the location of the point, some people find it is easier to use their thumb to apply the pressure.

Make sure to ask your health care provider exactly how to use these mind-body techniques.

[The nurse health coach will encourage and empower the patient that these are skills that can be used for relaxation, stress management and to build and sustain resilience. Coach will offer additional support as appropriate].

Would you like to continue to see a nurse health coach for further support to achieve your goals through lifestyle and behavior adjustments? [If so, patient will be referred for further support]

Please complete the program evaluation and your final survey; we would appreciate your feedback.

As discussed, you will also receive two brief surveys at the email you have provided. We will send you the survey after one and three months from the date you were discharged. Please take the time to fill them as your opinion is very important for us and the development of this program. ”